SECTION 5: 510(K) PREMARKET NOTIFICATION

Summary of Safety and Effectiveness Information

K132514 Kinsa Smart Thermometer

August 6, 2013

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) **Device name**

Trade name:

Kinsa Smart Thermometer

DEC 0 2 2013

Common name:

Thermometer

Classification Number/ Classification name/Product code:

Clinical electronic thermometers are class II devices under 21 CFR § 880.2910 (product code FLL) and are classified by the General Hospital Panel.

2) **Submitter**

Kinsa, Inc.
603 Greenwich Street #101B
New York, NY 10014

3) **Company contact**

Lael J. Pickett
Kinsa, Inc.
603 Greenwich Street #101B
New York, NY 10014
Telephone: 651-900-5460/Fax: 917-210-4288
Email: ljp1286@yahoo.com

4) **Classification**

Device class:

Class II

Classification panel:

General Hospital

Product code:

FLL

Special Controls:

Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

5) **Legally Marketed Device to which Equivalence is Claimed**

Fudakang Digital Thermometer (K101387)

6) **Comparison to Predicate Device**

Feature	Fudakang Digital Thermometer (K101387)	Kinsa Smart Thermometer (KXXXXXX)
Intended Use	Measurement and monitoring of human body temperature	Same
Indications for Use	Intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home. BT-A11CN, BT-A21CN and BT-A41CN can be used axillary measurement, oral measurements and rectal measurement.	The Kinsa Smart Thermometer is intended to measure the human body temperature orally, rectally, or under the arm, and the devices are reusable for clinical or home use on people of all ages.
Tip	Stainless Steel	Same
Tip Housing	Thermoplastic rubber	Same
Body Housing	Acrylonitrile butadiene styrene	Same
Size	4.9" long x 0.74" wide x 0.35" thick	Approximately 4.25" long x 0.5" wide x 0.3" thick
Weight	11 grams	4.4 grams
Flex Tip	Yes	Same
Power Source	Battery	Mobile device battery
Principles of Operation	Thermosensor/ASIC (Thermistor used as thermosensor)	Same
Compatible with Mobile Device (e.g. Smartphone)	No	Yes
Display °F or °C	Yes	Same
Reusable	Yes	Same
Measurement Range	32.0°C – 42.9°C	35.0 to 42.0°C
Accuracy	95.0°F – 102.0°F/±0.2°F	95.0°F – 107.6°F/±0.2°F
	35.0°C – 39.0°C/±0.1°C	35.0°C – 42.0°C/±0.1°C
Response Time	60 seconds	15 seconds
ASTM E1112-00	Compliant with ASTM E1112-00 (2006)	Compliant with ASTM E1112-00 (Reapproved 2011)
AAMI/IEC 60601-1:2005+A1:2012(E)	Compliant with IEC 60601-1	Compliant with AAMI/IEC 60601-1:2005+A1:2012(E)
AAMI/ANSI/IEC 60601-1-2:2007	Compliant with IEC 6061-1-2	Compliant with AAMI/ANSI/IEC 60601-1-2:2007

7) **Device description**

The Kinsa Smart Thermometer product is a thermometer that connects to a Smartphone or another mobile device (e.g. an iPod Touch). The product will read body temperature the same way a clinical digital thermometer does by being placed under the tongue in the mouth, rectum or alternatively, or under the arm. Like other clinical digital thermometers, the Kinsa Smart Thermometer is a thermistor-based product; however, it has the advantage of

being read on a mobile device display. Unlike other clinical digital thermometers, the Kinsa Smart Thermometer product requires no batteries or LCD displays. The Kinsa Smart Thermometer is reusable for clinical or home use on people of all ages.

The Kinsa Smart Thermometer will connect to Smartphones or other mobile devices via a headphone jack that accepts a microphone input. In this document the terms Smartphone, smartphone and mobile device are used interchangeably and are defined to include the following products: Apple iPhones 5, 4S and the Apple iPod Touch 5.

The Kinsa Smart Thermometer consists of four components:

A. Thermometer (probe).

B. An adapter to setup each Smartphone for temperature reading (only needed once per Smartphone).

C. An optional, flexible extension cord that can be used to lengthen the distance between the thermometer and Smartphone so users can see the Smartphone screen while taking a temperature.

D. Software.

8) Summary of technologies

The Kinsa Smart Thermometer works by sending out an audio signal. This signal crosses the thermistor in the metal tip of the thermometer and is altered based on the temperature. The device reads back the signal change through the mobile device's microphone input. The Kinsa Smart Thermometer app (application) has software to process the signal and displays the precise temperature on the screen. The Kinsa Smart Thermometer meets and exceeds ASTM standards for accuracy and meets ISO standards for accuracy.

The Kinsa Smart Thermometer has no batteries, processor or LCD display, instead leveraging the power, processor and display of the user's Smartphone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 2, 2013

Kinsa, Incorporated
C/O Lael J. Pickett
603 Greenwich Street, #101B
New York, NY 10014

Re: K132514
Trade/Device Name: Kinsa Smart Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 2, 2013
Received: September 4, 2013

Dear Mr. Pickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132514

Device Name
Kinsa Smart Thermometer

Indications for Use *(Describe)*
The Kinsa Smart Thermometer is intended to measure the human body temperature orally, rectally, or under the arm, and the devices are reusable for clinical or home use on people of all ages.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman
Date: 2013.11.29 12:42:36 -05'00'